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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/561,191

12/16/2005

Masayuki Tsuchiya

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EXAMINER

CARLSON, KAREN C

ART UNIT

PAPER NUMBER

1656

NOTIFICATION DATE

DELIVERY MODE

03/18/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/561,191	<b>Applicant(s)</b> TSUCHIYA ET AL.	
	<b>Examiner</b> Karen Cochran Carlson	<b>Art Unit</b> 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-16, 19 and 22-49 is/are pending in the application.
- 4a) Of the above claim(s) 1-16 and 24-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19, 22 and 23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

This Office Action is in response to the paper filed January 14, 2009.

Claims 1-16 and 24-49 are withdrawn from further consideration because these Claims are drawn to non-elected inventions. Claims 17, 18, 20, and 21 have been canceled. Claims 19, 22, and 23 are under examination.

**Repeat: Withdrawal of Rejections:**

The rejection of claims 19-23 under 35 USC 101 is withdrawn in view of the amendments and cancellation of claims 20-21.

The rejection of claims 19-23 under 35 USC 11, second paragraph, is withdrawn in view of the amendments and cancellation of claims 20-21 .

The rejection of claim 19-23 under 35 USC 102(b) is withdrawn in view of the cancellation of the claims 20-21 and amendments to the claims, where Luhn et al. do not teach Chinese hamster cell.

The rejection of claims 19 and 20-23 under 35 USC 103(a) is withdrawn in view of the cancellation of the claims 20-21 and amendments to the claims, where there is no motivation in Luhn et al. or Kao et al. in regards to suppression of expression of the fucose transported gene

**Maintenance of Rejections:**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 19, 22, and 23 are again rejected under 35 U.S.C. 102(e) as being anticipated by Kanda et al. U.S. 2004/0110282 (filing date April 9, 2003).

Kanda et al. teach a cell in which activity of GDP-fucose protein is decreased. See Abstract. In paragraph [0391] they teach that any host cell can be used in the method of suppression of fucose transporter as long as it has a gene encoding GDP-fucose transporter. In paragraphs [0009-0011] they teach that a Chinese hamster ovary cell (CHO cell) is used (**Claims 19 and 22**).

In paragraphs [0021], [0217] and [0284] they teach that a gene disruption technique that comprises targeting a gene encoding GDP-fucose transporter (**Claim 19**).

In paragraph [0036] they teach that RNA is introduced into the cell by using a vector. In paragraphs [0143] and [0286] they teach a target vector for homologous recombination or an RNA interference (RNAi) that targets GDP-fucose transporter where the gene disruption method may be any method that can disrupt the gene of the target enzyme (**Claim 23**). In paragraphs [0368] and [0376] they teach that the expression vector or vector that is autonomously replicable in the host cell can be

integrated into the chromosome, and that it comprises a promoter at such position that the designed RNAi gene can be transferred (**Claim 23**).

While Kanda et al. teach the cDNA encoding the Chinese hamster fucose transporter as SEQ ID NO: 35 – see also Examples 2+ - one skilled in the art would recognize that the CHO comprises the genomic DNA encoding this fucose transporter and that the use of RNAi or gene disruption refers to this gDNA regardless of what the specific nucleic acid sequence is.

Therefore, the claims are anticipated.

Applicants urge that Claim 19 has been amended to recite that the Chinese hamster fucose transporter gene having SEQ ID NO: 1 is disrupted and SEQ ID NO: 1 is not disclosed in Kanda et al. Given that Kanda et al. teach to use Chinese hamster ovary (CHO) cells and teach nucleic acid encoding Chinese hamster fucose transporter as SEQ ID NO: 35, the teachings of Kanda et al. continue to anticipate the Claims because one skilled in the art would recognize that the CHO cell comprises gDNA (which comprises the cDNA in total or in exon fragments) encoding the Chinese hamster fucose transporter. Thus, the nucleic acid sequence of SEQ ID NO: 1 is inherent to Kanda et al.'s teaching to disrupt this gene. See *In re Donahue* (226 USPQ 619) which sets forth that the art applied under 35 USC 102 must only sufficiently describe the claimed invention to be applied as prior art against the invention. *In re Schauman* 197 USPQ 5) the courts defined anticipation as the disclosure in the prior art

of a thing substantially identical with the claimed invention. Further, that no more is required of a reference than that it set forth the substance of the invention.

**New Objections and Rejections:**

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. See page 12, last sentence of para. 3. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19, 22, and 23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 19 has been amended to recite that the gene is both suppressed AND disrupted. This indicates that two events have happened at the nucleic acid, rather than a single event at the nucleic acid. The specification does not teach this invention; rather, the gene is either suppressed OR disrupted. Therefore, this amendment is new matter.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 19, 22, and 23 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 of copending Application No. 11793649. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are drawn to cells having the fucose transporter gene suppressed or disrupted.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

It is noted that Applicants have failed to disclose their related applications.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson whose telephone number is 571-272-0946. The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Karen Cochrane Carlson/  
Primary Examiner, Art Unit 1656